



⑯ Europäisches Patentamt
European Patent Office
Office européen des brevets



⑪ Publication number : **0 613 675 A1**

⑫

EUROPEAN PATENT APPLICATION

⑯ Application number : **94301605.5**

⑮ Int. Cl.⁵ : **A61K 7/00, A61K 9/70,
A61K 31/44**

⑯ Date of filing : **04.03.94**

⑯ Priority : **05.03.93 US 26883**

⑯ Date of publication of application :
07.09.94 Bulletin 94/36

⑯ Designated Contracting States :
AT CH DE FR GB IT LI SE

⑯ Applicant : **JOHNSON & JOHNSON
CONSUMER PRODUCTS, INC.
Grandview Road
Skillman, New Jersey 08558 (US)**

⑯ Inventor : **Salmon, Michael
37 The Waters Funtley
Fareham, Hampshire PO17 5EL (GB)**

⑯ Representative : **Fisher, Adrian John et al
CARPMAELS & RANSFORD
43 Bloomsbury Square
London WC1A 2RA (GB)**

⑯ Cosmetic applicator useful for cleansing, moisturizing and protecting the skin from diaper rash.

⑯ This invention relates to a cleansing cloth or applicator containing a low-viscosity antimicrobial emulsion useful in combatting the microorganisms that cause diaper rash.

EP 0 613 675 A1

Jouve, 18, rue Saint-Denis, 75001 PARIS

This invention relates to cosmetic applicators comprising absorbent sheets impregnated with an oil-in-water emulsion incorporating various cleansing and moisturizing agents which are particularly adapted to the effective cleansing and moisturizing of skin. These emulsions may also contain antimicrobial agents exhibiting activity against the causative organisms associated with diaper rash.

Background of the Invention

It has been shown that the most effective way of preventing diaper rash is to cleanse the skin thoroughly and to remove the microorganisms that have been identified as causative. The source of these microorganisms is often the fecal deposits that can remain on a baby's skin while wearing the diaper. Because fecal deposits consist of both water-soluble and oil-soluble matter, however, complete removal of fecal deposits from the diaper area requires both water-based and oil-based cleansing agents. Thus, it is an object of this invention to provide a mechanism for cleansing babies' skin in order both to remove waste deposits and to reduce the number of microorganisms available to cause infection.

A variety of treated cloths which are adapted for skin washing and cleansing are commercially available. Such products are composed of paper or non-woven fabric sheets which are wetted with an aqueous solution of water soluble or water dispersible ingredients. To cleanse skin thoroughly, both water soluble and oil soluble cleansing agents should be incorporated. Incorporating water-insoluble cosmetic ingredients in the form of an oil-in-water emulsion has been described in U.S. Patent 4,559,157 granted Dec. 17, 1985 to Smith et al., "Cosmetic Applicator Useful for Skin Moisturizing".

However, these prior-art emulsions are not very acceptable in that (1) they possess significant viscosity (1300 - 2000 cPs), which makes them difficult to use and which result in the emulsion remaining on the cloth rather than transferring to the baby's skin; or, (2) in cases where viscosity has been reduced, the compositions tend to be unstable. Thus, it has been difficult to make stable compositions that are low in viscosity and therefore acceptable for use on a cleansing cloth or wipe.

Accordingly, it is an object of this invention to provide a cosmetic applicator containing both water-soluble and water-insoluble cleansing agents and an antimicrobial agent, incorporated over and above the requirements for adequately preserving the product, which exhibits activity against the microorganisms that have been shown to be a factor in diaper rash, in a low viscosity, stable form.

It is a further object of the present invention to provide a cosmetic applicator containing ingredients capable of moisturizing skin.

It is a further object of the current invention to provide a cosmetic applicator containing antimicrobial agents possessing activity against the causative micro-organisms associated with diaper rash.

Other objects, advantages and novel features of the this invention will be apparent to those skilled in the art from the following description and appended claims.

Summary of the Invention

The objects of this invention are attained by providing a cosmetic applicator composed of a sheet of absorbent material which is impregnated with an antimicrobial oil-in-water emulsion. This oil-in-water emulsion contains an oil phase having a least one oil-soluble cleansing agent, at least one oil-soluble moisturizing agent and at least one oil based emulsifying agent dispersed in an aqueous phase. The aqueous phase contains at least one water-soluble detergent, at least one antimicrobial agent exhibiting activity against causative diaper rash micro-organisms and, optionally, some water-soluble emollients or humectants. Effective amounts of antimicrobial preservatives and fragrance may also be employed in the impregnating emulsion.

Such an emulsion would, when applied to the skin via a suitable applicator fabric, provide efficient cleansing of fecal deposits and leave on the skin a residual layer containing an antimicrobial agent capable of acting against the causative micro-organisms associated with diaper rash.

Other objects, advantages and novel features of the present invention will be apparent to those skilled in the art from the following description and appended claims.

Detailed Description of the Preferred Embodiments

The emulsions of this invention are formulated to be of very low viscosity to enable great flexibility in the choice of impregnation equipment and to enable the ready deposition of the emulsion on the skin.

The emulsions of this invention are formulated so that both the water-soluble and oil-soluble cleansing agents are made available to be deposited upon the skin when the impregnated sheet is pressed or rubbed against a skin surface. Further, the emulsions of this invention have been formulated so that both the oil-soluble and water-soluble moisturizers and emollients and antimicrobial agents are deposited when the impregnated sheet is pressed or rubbed against a skin surface.

In order to create emulsions that are stable during, and subsequent to, manufacture, the emulsions can be formulated by dispersing an oil phase comprising one or more oil-soluble cleansing agents and one or more oil-soluble moisturizing agents and one or

more oil-soluble emulsifying agents in an aqueous phase comprising one or more water-soluble cleansing agents and an antimicrobial agent exhibiting activity against causative diaper rash micro-organisms. The aqueous phase may further contain one or more water-soluble moisturizing agents or one or more water-soluble moisturizing agents or humectant. Both the oil phase and the aqueous phase may also incorporate antimicrobial agents in combined amounts effective to prevent bacterial, yeast or fungal growth in the applicators during storage. The emulsions of the present invention may also incorporate an effective amount of fragrance.

Therefore, the emulsions of the present invention preferably will comprise between about 4% and about 50% by weight of active ingredients, i.e. the water-soluble and oil-soluble cleansing agents, emulsifiers, moisturizers, humectant, emollients, antimicrobial agents, fragrance and preservatives; and between about 50 and about 96% water, preferably distilled or deionized water.

About 3% to about 20% of the active ingredients will be present in the oil phase of the emulsion, while the remainder of the active ingredients will be fully soluble in the aqueous phase.

The emulsions useful in this invention are formulated from an oil phase which incorporates one or more oil-soluble cleansing agents. These cleansing agents are preferably present in an amount of between about 0.5% and about 10% by weight of the entire emulsion.

Oil-soluble cleansing agents function to remove fatty deposits from the skin which are either difficult or impossible to remove using water-soluble detergent cleansers. The oil-soluble cleansing agents useful in the practice of the present invention include those commonly employed in cleansing creams and lotions, such as liquid hydrocarbons such as mineral oil, paraffinic derivatives and the like. In the practice of this invention, iso-paraffins are preferred and may consist of one or more of the commercially available grades such as Isopar-L (Esso Chemical Company U.K.). The iso-paraffin should be present in the amount of about 0.5 to about 10% by weight of the emulsions of the present invention.

The oil phase of the emulsions of the present invention will also include one or more oil-soluble moisturizing agents which are preferably present in an amount between about 1% and about 8% by weight of the entire emulsion. The oil-soluble moisturizing agents useful in the practice of the present invention include those commonly employed in moisturizing creams and lotions such as liquid hydrocarbons such as petrolatum, mineral oil and the like, vegetable and animal fats and oils such as lanolin and its derivatives, vegetable oils and their derivatives, esters and the like. In the practice of the present invention, mineral oils are preferred and may consist of one or more

of the commercially available grades such as Carnation White Mineral Oil (Witco Chemical Corporation).

The oil phase of the emulsions of the present invention should also include one or more oil-soluble emulsifying agents. These emulsifying agents should preferably be present in an amount between about 1% and about 7% by weight of the entire emulsion. The oil-soluble emulsifying agents useful in the practice of the present invention include those non-ionic species utilized in the stabilization of cosmetic creams and lotions that contribute little viscosity to the finished formulation e.g. ethoxylated fatty acid-polyol esters, ethoxylated fatty alcohols and fatty esters.

In the practice of this invention, a combination of two or more oil-soluble emulsifying agents is preferably used to improve the stability of the emulsion.

The emulsions of this invention will also preferably include one or more water-soluble emollients or humectant such as polyhydric alcohols, water-soluble lanolin derivatives or the like. In the practice of the present invention polyhydric alcohols such as propylene glycol, glycerin and sorbitol and the like are preferred. The water-soluble emollients or humectant should be present in an amount between about 0.1% and about 8% by weight of the entire emulsion, preferably in the range of between about 0.5% and about 5.0%.

The emulsions of this invention will also include one or more water-soluble detergents or surfactants. These ingredients function both as aqueous water phase cleansing agents and wetting agents for the oil phase ingredients to allow uniform spreading on the skin. The most useful groups of water-soluble detergents are those classified as non-ionic such as ethoxylated sorbitan esters. Detergents that are found not to disturb the stability of the emulsion, including such detergents that are classified as amphoteric, such as imidazoline derivatives, are useful. Those water-soluble detergents or surfactants classed as anionic and cationic may be utilized in the present invention, provided that they do not disturb the stability of the emulsion. However, these anionic and cationic surfactants are not preferred for use in the products of this invention due to their potential to irritate skin.

The water-soluble detergents will preferably be present in an amount between about 1% and about 5% by weight of the entire emulsion.

The emulsions of the present invention will also include one or more bactericidal preservatives in a combined amount to prevent microbial and fungal growth both prior to impregnation and after impregnation. The preservatives useful in the practice of this invention are those commonly used in the formulation of cosmetic creams and lotions (parabens, imidazolidinyl urea, 5-chloro-2-methyl-4-isothiazolin-3-one with 2-methyl-4-isothiazolin-3-one and the like). Pre-



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention EP 94 30 1605
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.CLS)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X	DIALOG INFORMATION SERVICES, INC. FILE 669, FEDERAL REGISTER. AN=00082559. Topical antimicrobial drug products for over-the-counter human use; proposed rulemaking for diaper rash drug products. Vol 55, No. 119, Part V, June 20, 1990. * the whole document *	1-8	A61K7/00 A61K9/70 A61K31/44
X	NATUSAN, PRODUCT INFORMATION * Composition *	1-10	
D, X	US-A-4 559 157 (J.A. SMITH) * column 4, line 4-10 - column 4, line 30-36; claims *	1-10	
X	EP-A-0 328 355 (RICHARDSON VICKS, INC.) * column 1, line 56 - column 2, line 33 * * column 4, line 22 - column 5, line 7; claims *	1-10	
X	WO-A-91 04730 (SOLARCARE INCORPORATED) * page 10, line 1-5 - page 10, line 16-20; claims *	1-10	
		-/--	
TECHNICAL FIELDS SEARCHED (Int.CLS)			
A61K			
INCOMPLETE SEARCH			
<p>The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims</p> <p>Claims searched completely :</p> <p>Claims searched incompletely :</p> <p>Claims not searched :</p> <p>Reason for the limitation of the search:</p>			
<p>see sheet C</p>			
Place of search	Date of completion of the search		Examiner
THE HAGUE	1 June 1994		Orviz Diaz, P
CATEGORY OF CITED DOCUMENTS		<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons A : member of the same patent family, corresponding document</p>	
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p>			



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number

EP 94 30 1605

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cls)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
X, Y	MICROMEDEX, INC., DENVER, COLORADO, FILE MARTINDALE-THE EXTRA PHARMACOPOEIA * Cetylpyridinium chloride, products CITROEN TOWEL, GENTLEES *	1-10	
X, Y	V-I VADEMECUM INTERNACIONAL, MEDICOM S.A., MADRID * page 506, SILIDERMIL *	1-10	
			TECHNICAL FIELDS SEARCHED (Int.Cl.)



EP 94 30 1605

-C-

MEANINGFUL SEARCH NOT POSSIBLE

OBSCURITIES, INCONSISTENCIES

The expression "antimicrobial agent" is not sufficient to characterize specific chemical compounds.

In view of the large number of substances encompassed by this term, the search was limited to the general concept and to the specific compounds mentioned in the examples (EPC, art. 84; Guidelines for Examination in the European Patent Office, Part B, Chapter II.7, last sentence and Chapter III.3.7).